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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,605	08/14/2007	Haruo Sugiyama	14875-170US1 C1-A0403P-US	4985
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EXAMINER				
BELYAVSKIY, MICHAEL A				
ART UNIT		PAPER NUMBER		
1644				
NOTIFICATION DATE		DELIVERY MODE		
08/30/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/594,605

Applicant(s)

SUGIYAMA ET AL.

Examiner

Michail A. Belyavskiy

Art Unit

1644

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5 and 9-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SI/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Interval Patent Application
- 6) ☐ Other: _____

RESPONSE TO APPLICANT'S AMENDMENT

1. Applicant's amendment, filed 07/27/10 is acknowledged.

Claims 1-17 are pending.

Claims 2, 6-8 stand withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonselected inventions.

Claims 1, 3-5 and 9-17 read on the method of separating hepatic, endothelial or hematopoietic progenitor cells from cell population, comprising detecting the expression of WT1 gene are under consideration in the instant application.

3. An English translation of the foreign priority document Japanese Patent Application 2004-096744 is acknowledged.

The following new grounds of rejection is necessitated by the amendment and IDS filed on 07/27/10

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1,3-5 and 9-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP0846949 (IDS) in view of Fraizer et al (Blood, 1995, v.86, pages 4704-4706) and WO' 97/39354 (IDS) or Menssen et al (Blood, 1997, v.89, pages 3486-3493, IDS) , or Baird et al (Exp Hematol, 1997, v.13, pages 1311-1312, IDS) or Loeb et al., (Leukemia, 2003, v.17, pages 965-971) or Tsubio et al (Leukemia Research, 1999, v.23, pages 499-505)

EP 949 teaches a method of detecting and separating a specific cells from the cell population based on the level of expression of WT1 gene (see entire document, Abstract and pages 3, and 5 in particular). EP 949 teaches that said cells can be CD34- cells or solid cancer cells (see page 5 and 6 in particular).

EP 949 does not explicitly teaches a method for separation hepatic, endothelial or hematopoietic progenitor cells from the cell population, based on the level of expression of WT1 gene.

Fraizer et al., teach the high level of expression of WT-1 gene in a population of hematopoietic progenitor cell (see entire document, Abstract in particular). Fraizer et al., teach that expression of WT1 may be used as a clinical marker for immature MB cells expressing a high level of WT1 (see page 4705 in particular).

WO'354 teaches the high level of expression of WT-1 gene in a population of hematopoietic progenitor cell (see entire document, Abstract in particular).

Menssen et al ., teach the high level of expression of WT-1 gene in a population of hematopoietic progenitor cell (see entire document, page 3486 in particular). Menssen et al., teach that expression of WT1 may be used as a clinical marker for immature CD34+ cells expressing a high level of WT1 (see page 3487 in particular).

Baird et al., , teach the high level of expression of WT-1 gene in a population of hematopoietic progenitor cell (see entire document, Abstract in particular). Baird et al., teach that expression of WT1 gene was detected by using expression of WT1 gene.

Loeb et al ., teach the high level of expression of WT-1 gene in a population of hematopoietic progenitor cell (see entire document, abstract and page 969 in particular). Loeb et al., teach that expression of WT1 gene was detected by using expression of WT1 gene.

Tsuboi et al ., teach the high level of expression of WT-1 gene in a population of hematopoietic progenitor cell (see entire document, page 3486 in particular). Tsuboi et al ., teach that expression of WT1 may be used as a clinical marker for immature CD34+ cells expressing a high level of WT1 (see page 504 in particular). Tsuboi et al., teach that expression of WT1 gene was detected by using expression of WT1 gene.

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All the claimed elements were known in the prior art and one skill in the art could have combine the elements as claimed by known methods with no change in their respective function and the combination would have yield predictable results to one of ordinary skill in the art at the time of the invention (see *KSR International Co v Teleflex Inc.*, 550U.S.-, 82 USPQ2d 1385, 2007).

Thus it would have been obvious to one of the ordinary skill in the art at the time the invention was made to use expression of WT1 gene as a marker for separation hematopoietic progenitor cells from the cell population with a reasonable expectation of success because the prior art suggests that high level of expression of WT-1 gene in a population of hematopoietic progenitor cell and thus can be used as a marker to separate the cells expressing WT1 gene by the method taught in the prior art of EP'949.

From the combined teaching of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

8. No claim is allowed.

9. Applicant's amendment and submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609(B)(2)(i). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on 571/272-0735

The fax number for the organization where this application or proceeding is assigned is 571/273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michail A Belyavskiy/
Primary Examiner, Art Unit 1644